21 pts. (28.5%) had minor response or no change (NC) and 6 out of 21 pts. (26.9%) had progressive disease. Time to progression was 43.2 + 3.9 weeks (for pts. with CR and PR-54 ± 3.67 (n = 9); for NC-35.2 ± 9.5 (n = 6); for pts. with progressive disease 10.1 ± 6.4 (n = 6)).

Treatment toxicity: leucopenia-73.9% (grade III–IV – 14.2%); anemia-34.7%; thrombocytopenia-8.6%; diarrhea grade II – 18.5%; stomatitis and esophagitis – 7.4%; vomiting – 77% (grade III–IV – 58.8%); alopecia – 85.1%.

Conclusion: TMP combination has evident antitumor activity in advanced gastric cancer. The toxicity of this regimen is moderate.

1266 POSTER

Gemcitabine in advanced pancreatic cancer: A phase II trial

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Purpose: To assess clinical efficacy and safety of gemcitabine in advanced pancreatic cancer.

Methods: From April 1995 to December 1996, 24 consecutive pts (13 female and 11 male, median age 64 yrs) with pancreatic carcinoma entered this phase II study. ECOG PS was 0 in 6 pts, 1 in 8 pts, 2 in 6 pts, and 3 in 4 pts. 15 pts had metastatic and 8 locally advanced unresectable disease. 19 pts did not receive any previous treatment, and 5 received first line chemotherapy with 5-fluorouracil. Gemcitabine 1000 mg/m^2 was administered iv in 30′ in the first cycle once weekly for up to 7 weeks followed by 1 week rest; then in subsequent cycles, once weekly for 3 of every 4 weeks. The median number of cycles administered was 4 (range 1–10); 3 pts received only 2 doses because of early progression or refusal, but they have been included in the clinical efficacy analysis.

Results: 4 pts obtained partial response (16%) and 10 (41%) stable disease; 10 pts experienced progressive disease. PS improved in 11 pts (46%); analgesic consumption was reduced in 10 pts (41%). In the majority of pts, treatment was well tolerated and all pts were treated on an outpatient basis. Toxicity was mild and mainly consisted in moderate and quickly reversible myelosuppression: we registered 3 episodes of WHO grade III–IV thrombocytopenia and 2 episodes of grade 3 leukopenia. Grade 3 anemia was noted in 2 pts. Systemic toxicity was irrelevant with 7 pts complaining of fever (grade 1–2) and 7 of mild astenia during treatment.

Conclusion: We conclude that gemcitabine chemotherapy was very well tolerated and determined a significant clinical improvement with modest antitumoral activity in pts with advanced pancreatic cancer.

1267 POSTER

Gastro-oesophageal smooth muscle tumors: Treatment and analysis of prognostic factors

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Purpose: Gastro-oesophageal smooth muscle tumors show a variaty in clinical presentation and prognosis and the optimal method of treatment remains unclear.

Methods: We studied retrospectively the clinicopathological data to determine the effect of surgery, the time to recurrence and survival.

Results: Between 1986 and 1996 we treated 61 patients (27 ♂, 34 ♀) with a gastro-oesophageal smooth musle tumor [38 pts leiomyoma (LM) (62%): 15 pts low grade leiomyosarcoma (LMS) (25%); 8 pts high grade LMS (13%)]. Age ranged from 18 to 87; mean 59 years in LM and 61 years in LMS. The mean tumor diameter was 4.6 (1–11) cm in LM and 8.3 (3–18) in LMS. Patients often complained of abdominal pain (63%) and gastrointestinal bleeding (59%). In 15 pts the LM were asymptomatic. LMS were situated at the distal oesophagus (3 pts); at the fundus (10 pts); at the corpus (7 pts) and at the antrum (3 pts). Of the 23 LMS, 12 pts underwent a complete resection and 7 pts a microscopic incomplete resection. At a median period of 15 months, 4 of the 13 resected low grade LMS and 5 of 6 resected high grade LMS recurred, usually in the liver. The median survival was 66 (6–128) months in low grade LMS and 16 (2–48) months in high grade LMS. The overall 5-year survival was 35% (75% low grade LMS, 0% high grade LMS (p = 0.023). Age, sex, tumor size and site had no effect on survival. Differentiation and radicality had a significant prognostic effect (p = 0.02).

Conclusion: Prognosis of gastro-esophageal smooth musle tumors mainly depends on tumor grade and free surgical margins. Even after microscopic complete resection high grade LMS had a negative influence on the survival. Studies with adjuvant treatment such as intraoperative radiotherapy and chemotherapy are needed to improve these results.

1268 POSTER

Gemcitabine (GEM) and 5-fluorouracil (5 FU) in advanced pancreatic cancer: A GISCAD phase II study

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Purpose: In a randomized clinical trial (Moore, ASCO 96), GEM has been shown to be more effective than 5 FU, the most common drug used in advanced pancreatic cancer. GEM and 5 FU work in different ways to inhibit DNA and RNA synthesis: from a theoretical point of view, their combination could result in higher response rates. To test this hypothesis, a two stage phase II study was initiated in November 96.

Methods: End points: response rate, clinical benefit (Andersen, ASCO 94) and toxicity. If objective responses and/or evidence of clinical benefit were observed in at least 5 of 13 patients, further 30 patients should be accrued. Schedule was: Gem 1000 mg/m^2 and 5 FU 600 mg/m^2, weekly for 3 weeks every 4.

Results: Characteristics of the first 13 patients were: 10 male and 3 female; median age 57 years (range 47–72 years); 4 patients had locally advanced disease, 4 had metastatic disease and 5 both sites of disease. In these 13 patients, we obtained 1 partial response and 5 clinical benefits. Side-effects were mild: no gastrointestinal toxicity or grade 3–4 (WHO) hematological episodes were recorded. We observed only two episodes of grade 2 (WHO) leukopenia and 1 of thrombocytopenia.

Conclusions: These results allowed the starting of the second step. Up to day (February 97), 7 further patients have been enrolled.

1269 POSTER

Aortic-stop-flow-infusion (ASF) in patients with unresectable pancreatic cancer

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Purpose: Chemotherapy in patients with pancreatic carcinoma remains disappointing. A suitable method to achieve an effective drug-concentration in the target tissue without causing the side-effects of a high-dose systemic chemotherapy seems to be the isolated hypoxic perfusion of the abdomen (ASF).

Methods: In a two-year trial ASF was performed in 17 patients (5 female, 12 male) with unresectable pancreatic cancer. In general anaesthesia the separation of the abdominal organs from systemic circulation was achieved by transfemorally inserted balloon-catheters into the aorta and vena cava. The infusion of 40 mg of Mitomycin C was followed by a hypoxic perfusion over 20 minutes. Response was evaluated by CT-scan after 6 weeks.

Results: In 20 perfusions no toxicity-related deaths were observed. Nausea and vomiting (10 episodes WHO ≥ III) were the most frequent toxicities. In 5 patients (28%) a deep-vein thrombosis occurred. No partial or complete remission was observed, a disease stabilization was achieved in 3 patients. The median survival after ASF was 4.2 months (range 1.3–21) without a significant influence of metastatic disease.

Conclusions: Inspite of some hopeful reports about regional therapy in pancreatic carcinoma ASF did not influence response or survival and showed clinically relevant side-effects. Due to these disappointing results we decided to stop this trial.

1270 POSTER

ELFE (etoposide, folinic acid, 5-fluorouracil, and epirubicin) regimen in the treatment of advanced pancreatic cancer (APC)

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Purpose: Pancreatic carcinoma is generally considered a chemotherapy-resistant malignant neoplasm and to date there is no established chemotherapeutic treatment for patients with advanced disease. Many new combi-